Stakeholder Meeting 7/13/11

Welcome – Carol Smith

Introductions by the group

Attendees

Jeff Bailey – Inman WWTP
Clint Elliott – Grand Strand Water & Sewer
Cheryl Johnson – Pace Analytical Huntersville
Phillip Thompson King – Chester Sewer District
Jeff Czarnecki – Greenville Water System
Jason Collins – Keowee Key Utility Systems
Billy McCain – City of Rock Hill
Deborah Edwards – City of Rock Hill
Melissa Robbins – City of Rock Hill
Tony Young – Chester Sewer District
Ted Millings – Savannah River Nuclear Site
John Young – Savannah River National Laboratory
Patrick Timms – Chester Sewer District
Lee Slusher – Milliken & Company
Dina Mauldin – CH2M Hill
Maureen Gillespie – Giant Cement
Thomasena Simmons – BP Chemical
Bruce E Watt – Data Resources
Rudy Powell – Davis & Floyd
Bob Pullano – GEL
Van Ward – Davis & Brown
Cheryl Sommers – Commonwealth Laboratories
Jestin deWerdt – Mount Pleasant WaterWorks

SCDHEC Stakeholders
Lab Certification
Chris Cole – BES
Cynde Devlin – BLWM
Crystal Rippy – BOW
Tabatha Corley – BES
Mary Ann Fuller – BOW
Judy Graham – BES
Michael Mattock – BES
Leigh Plummer - BES
Sandra Flemming - BES

Subcommittee Reports – Brief update from Chairs

Personnel Qualifications – Jamie Berry for Alan Clum

Competency of the staff

Performance criteria
Annual Training – Ethics, proficiency
Different sizes of labs
Experience vs. Education
Using other states guidance

Quality Systems – Bob Pullano

Created the section based on Wisconsin's Regulation and how to pull it all together
Discussion on the different aspects of this section
Have a good starting point and would like feed back from the Group

Data Reporting – Cheryl Johnson

Defining what should be in a laboratory report
Requirements for a final report and in-house laboratories
Biggie- data reporting criteria
How do we qualify data and notify the client and program area
Guidance on how laboratories can handle each situation for sample reporting

Sample Collection/COC – Jason Collins

Wisconsin Regulation was used to start
Main topic – temperature upon receipt, blue ice, temperature integrity

Field Parameter – Carol Smith for Heather Beard

"Field parameter laboratories" must meet the same requirements as other laboratories, therefore it was decided to remove this type of lab designation.
Will do away with "field parameter laboratories" and refer to it as field measurements that are performed by a certified laboratory (commercial, municipal, industrial, State, Federal).
At this time, the primary calibration of field equipment must be performed at the certified laboratory using the equipment and buffers that have been stored at the certified laboratory.
Working on how laboratories can meet the requirements of daily calibration to alleviate the impact of excessive travel costs. This is under consideration by the subcommittee at this time.
Would like feedback from other stakeholders concerning other options.

Phillip Thompson-King and Jeff Bailey expressed interest in serving on the Field Parameter subcommittee.

Definitions – Thomasena Simmons

Several references were used to come up with definitions
Quality assurance definitions did create some problems
Waiting to finish the regulation to finish this portion
The current definitions will remain until the Regulation is complete and then terms will be defined as requested by the subcommittees.

Concerns from the last October 28, 2010 Stakeholder Meeting

Carol Smith reviewed the various regulation concerns addressed by the Stakeholders during the Stakeholder meeting of October 28, 2010.
More structured
Consistency with other states

Ensure quality data is still produced with new Regulation
Address all types of laboratories
Some people didn't know DHEC had reporting limits
Consistency with terminology between states and methods
Don't want to reinvent the wheel
Use NELAP Standards
Don't use NELAP Standards
More communication between certification program and permit program areas
Include EQC Regions in the meeting because of inconsistencies
Don't make the Regulation cost prohibitive
Certify analyst or location
What is a laboratory?
Sample traceability
Electronic Data Deliverables
Qualifiers
In-State and Out-of-State Evaluations
How do we certify out-of-state labs?
Adding new compounds and methods reported to program areas

Stakeholder Committee consists of 30 internal and 30 external stakeholders meeting on a monthly basis.

Schedule for the Regulation Development – Carol Smith

Notice of drafting lasts one year. Another NOD is being published July 22, 2011.
It is not possible to complete the Regulation process to submit to the DHEC Board and have the regulation to the General Assembly by January 2012.
The process of regulation development includes a staff informational forum concerning the proposed regulation then a public meeting before the DHEC Board. The Board must approve it before it goes to the General Assembly.

Stakeholder Comments:
What time frame are we targeting? And how is the new board affecting our Regulation?
Anticipating submitting the Regulation by the 2013 Legislative session
The Board will be basing their approval on the information we present to them. We must document all comments from our stakeholders and they will be reviewing this information prior to approval of the proposed regulation. We must also have support from the regulatory community (laboratories).

Framework of the Regulation – Carol Smith

Discussion on the Regulation outline document provided to the Group

What is the intent of the Regulation? It is currently very specific in some sections for example temperature checks and general in other sections for example MDLs.

> QA/QC such as MDLs is being held off for EPA to issue the essential QA/QC requirements.

Does EPA need to sign off on SC Regulation?

> EPA will be consulted because they evaluate SC Certification Program.

We want to avoid having to develop policy by having specifics in the regulation.

We will include the table of contents into the Regulation.

We would like to utilize the requirements addressed within the methods, so it does not need to be dictated in the Regulation. Problems are encountered for those methods without the essential QA/QC.

Topics of Discussion concerning the Regulation Draft

Scope:

Air Quality not mentioned

The original scope was more specific and was preferred over the more generalized scope in the draft.

Asbestos – the regulation as it reads now states that it must be performed by a certified lab

The scope covers everything in a general way by including language "required by the Department"

Lost "environmental quality evaluations" when updating the scope – DHEC program areas

What is Environmental Quality Assessment or Evaluation?

Add waste characterization because it's not included with the draft language or a definition for "Environmental Evaluations" (to include waste characterization)

Concerns that the Regulation will require that storm water analyses be performed by a certified lab, but the stormwater regulation is in conflict with this. What about the pretreatment analyses required by the cities and counties. Does the regulation cover this?

Remove "environmental" in order to generalize it even more

Purpose:

"To evaluate and certify an environmental laboratory" – what if they are not environmental such as industrial. Drop "environmental"

The original statement because of "validity and quality" because it is the purpose of this Regulation

Original is too broad because the "validity" is not part of our program responsibility.

Too specific. Remain general. Does not need to include the responsibilities of other program areas.

Personnel Qualifications:

Add pH, DO, and temperature to the Regulation and get rid of the waiver

Concerns with shall and should

Define “may”

Cost that this will add to the laboratories

A – this is not included in the SOP

N under SOP covers this

Qualifications for Supervisor?

Remove “laboratory supervisor”

Why do sampling personnel of a certified laboratory have to be trained and not sampling personnel for a non-certified laboratory?

This involves other regulation changes beyond laboratory certification

Do other states require qualifications for analyst?

Consider certifying analysts.

“Shall” for laboratory director could pose a legal problem

Training records must be kept indefinitely…is too long

Change the “indefinitely” – We deleted the word “indefinitely.

Quality Manual:

No comments

Certification Criteria:

Can you not use other approved methods that are not listed in the federal and state regulations as listed in 1.a?

Next section covers any other methods

Facility:

D is unnecessary and should be removed

Equipment:

vi (last sentence) and vii (first sentence) needs to be reworded.

iii. add “or replaced”

viii move to as a part of vii in order to refer to balance and not all equipment

iv does not address dial, IR, or digital thermometers

What about titrators, amperometric titrators, manual equipment

Safety: Should this be included in the Regulation?

Waste Disposal: Should this be included in the Regulation?

SOP:

Is a frequency of review going to be addressed?

Section a. under SOP, discussed taking out requirements under "General"

Section b.i. discussed that there were other procedures besides test methods that would have an SOP

Section b.ii. – need to add document control procedures

Section b.iii.(N) – add reference to section 7

Incorporate an annual review into the Regulation.

Elaborate on A-R

Address the expiration dates of reagents and standards

i – language to include other SOP other than test methods. Instead of test methods add activities. a.i uses the same language.

ii – removed "manual". Address document control procedures.

Removed should under General Requirements.

N – reference section 7

Essential QA/QC:

"the written methods" – shouldn't this be SOP instead of method?

This section should be removed to reference federal regulations

This section needs more input from stakeholders. We also need to wait to determine what the final regulation will specify.

Sample Collection Preservation and Handling:

Blue Ice/As received on ice – do laboratory's use blue ice, what steps do laboratory's take

If samples are getting to laboratory at temperature however it's cooled

Data Reporting:

The issue of using the NC process to let the Department know when a sample is received in violation of the sample collection, preservation, and holding time requirements, but the lab si requested by the client to analyze them anyway.

Highlighted "internal clients" – some discussion on this.

Discussed laboratories having to report any samples not meeting holding time or preservation requirements to the Department

Laboratories will lose clients if they are forced to "tell on them" to the DHEC.

The notification will be used to give laboratories more leverage with the clients by having to report samples that the clients have requested be analyzed even though it is out of holding time or not meeting sample preservation requirements.

As a client I would not want to be reported to DHEC if I chose to analyze a sample out of holding time that I plan to use for process control.

Brings up the issue on non-compliance samples being noted on the chain-of-custody.

Clients requesting the analysis of regulatory compliance samples exceeded the holding time or not meeting the preservation requirements would be the only samples being reported to the program area.

DHEC program areas find it would be helpful to receive information such as this to make sure the data that is received can be used.

The discussion of this section will continue in the next meeting.

The next Stakeholder Meeting is tentatively scheduled for August 30th. An announcement will be placed on the website once a meeting room has been reserved.

Comments concerning the draft document should be submitted via the LabCertHelp e-mail address or by submitting them to the Lab Certification Program.